Med-Tox Group
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September 11, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket 02N-0276

Dear FDA:

Ephedra 'food supplement' manufacturer, marketer and distributor records revealed in litigation discovery indicate a clear and present danger, vis a vis the products themselves when used as directed as well as their abuse as likely vehicles for bioterrorism.

The intentional adding of dangerous drugs and controlled substances to food supplements typically made from poorly-defined materials from unknown and unregistered suppliers for sale to misled consumers appears to be exemplify an insidious form of bioterrorism.

Not only are hundreds-thousands of product defect reports and tens of thousands of 'secret' AERs indicated, their record keeping, product testing and quality assurance are abysmal. Ephedra pushers are in no position, nearly eight years after DSHEA passage and decades after FD&C Act passage, to responsibly or accurately assure safety from a bioterror threat.

In addition to registration and certification from company executives about appropriate monitoring of their products, ephedra pushers should also be required to register with FDA the many suppliers in their convoluted scheme to concentrate dangerous drugs and controlled substances in their food products.

Falsified registrations and certifications should be more prominently prosecuted. Certainly, the current criminal probe of Metabolife International for its false statements to federal and state government agencies is merely the tip of the iceberg. Certainly, the US Department of Justice should have the full range of the discovery documents I have reviewed.

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Trade associations defending these illegal and dangerous products should be required to register their purported inspections of ephedra product manufacturers as part of their bogus 'quality' certifications, and be investigated for RICO violations.

Retailers who prepare in any way any ephedra product should register, and certify.

My comments apply similarly to all dietary supplements, particularly those manufactured by individuals and companies with little if any 'good manufacturing' skills.

Properly, CHPA on behalf of supplement suppliers and marketers noted in its 9/4/02 comments to this docket, "...the FD&C Act also defines the term "dietary supplement," and prescribes that for most purposes, a dietary supplement shall be deemed to be a food within the meaning of this Act. Thus, it is clear that the provisions of the Act that relate to food are generally intended to cover dietary supplements as well." CHPA and other trade associations should, therefore, stop promulgating the false and illegal notion that dietary supplements need not be proven safe prior to marketing as prescribed by DSHEA.

I attach my recent invited article about DSHEA abuse, which appropriately appeared in the FDLI Update issue focused on bioterrorism (May/June 2002, www.fdli.org/pubs/Update/toc/2002/issue3.html).

Sincerely,